UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Norfolk Division

CAREFIRST OF MARYLAND, INC., *et al.*, on behalf of themselves and all others similarly situated,

Plaintiffs,

v. **Case No. 2:23cv629**

JOHNSON & JOHNSON and JANSSEN BIOTECH, INC.,

Defendants.

ORDER

Before the Court is Carefirst of Maryland, Inc., Group Hospitalization and Medical Services Inc., and Carefirst Bluechoice Inc.,'s (collectively, "Plaintiffs") Motion to Compel Production of Documents and accompanying memorandum in support. ECF Nos. 93, 95. Therein, Plaintiffs seek to compel Johnson & Johnson and Janssen Biotech, Inc. (collectively, "J&J") to produce documents in response to Plaintiffs' Request for Production Nos. 1–2, 78–83, 85–88, 90–92, and 101. ECF No. 93. J&J filed an opposition to the Motion to Compel, ECF No. 99, Plaintiffs filed a reply, ECF No. 102, and J&J filed a court-authorized sur-reply. ECF No. 110. The Court held a hearing on the Motion to Compel on August 20, 2024. Accordingly, the Motion to Compel is fully briefed and ripe for disposition. For the reasons explained below, Plaintiffs' Motion to Compel, ECF No. 93, is **GRANTED IN PART** and **DENIED IN PART**.

I. FACTUAL AND PROCEDURAL BACKGROUND

Plaintiffs represent a proposed class of end payers who allege that J&J unlawfully delayed the introduction of biosimilar competition for ustekinumab—sold under the brand name "Stelara"—which is used to treat certain autoimmune diseases. ECF No. 36 at ¶¶ 1, 2. Plaintiffs

allege that J&J took a series of unlawful actions which violated, and continue to violate, Section 2 of the Sherman Antitrust Act, state antitrust laws, state consumer protection laws, and state common law. *See id.* at ¶¶ 4–8, 323, 334, 355, 373, 392, 404. Plaintiffs contend that J&J unlawfully delayed the introduction of biosimilar competition to Stelara in two ways. *Id.* at ¶¶ 4–8. First, that between 2019 and 2021, J&J defrauded the United States Patent and Trademark Office ("USPTO") into incorrectly issuing a method-of-use patent covering the use of ustekinumab to treat ulcerative colitis ("the '307 patent"). *Id.* at ¶ 5. Second, that in 2020, J&J purchased a portfolio of patents from a company called Momenta, which purportedly assist in manufacturing drugs that are biosimilar to ustekinumab, and that J&J subsequently enforced those patents to keep competition out of the market. *Id.* at ¶¶ 7–8.

After several meet and confer conferences to resolve discovery disputes, Plaintiffs filed the instant motion seeking an order compelling J&J to produce of two categories of information: (1) organizational charts dating back to 2011 (RFP Nos. 1–2); and (2) documents and data necessary to assess J&J's market power dating back to 2011 (RFP Nos. 78–83, 85–88, 90–92, and 101).[1] ECF No. 95 at 11–21. Generally, Plaintiffs argue that discovery for these RFPs dating back to 2011 is relevant because most of Plaintiffs' allegations involve events that occurred before 2018, including the launch of Stelara in 2009, the beginning of the key clinical trial studying the use of ustekinumab to treat ulcerative colitis in 2015, and the launch of a number of other drugs that are used to treat the same autoimmune conditions as Stelara (described by Plaintiffs as "potential therapeutic competitors" and identified at ECF No. 95 at 18 n. 49) before 2018. *See id.*

[1] Plaintiffs' Motion to Compel initially requested that the Court compel J&J to produce documents regarding RFP Nos. 7–13, involving J&J's '734 patent, which covers the composition of ustekinumab. ECF No. 95 at 21–22. However, in their reply, the Plaintiffs stated that the parties reached a compromise as to the scope of those RFPs, and withdrew their motion with respect to those RFPs. ECF No. 102 at 5.

In opposition, J&J generally argues that documents dating back to 2011 are irrelevant to the question of whether J&J possessed monopoly power in 2022 or 2023—the timeframe J&J contends is the relevant period to evaluate Plaintiffs' antitrust claims. ECF No. 99 at 12–17. J&J also argues that producing documents dating back to 2011 would be unduly burdensome based on the volume of documents and hours of time that would be needed to review the documents. *Id.* at 17–18. As such, J&J contends the requested discovery is not proportional to the needs of the case.

In their reply, Plaintiffs reiterate the relevance of the documents they seek, and argue that J&J has failed to establish that the requested discovery is unduly burdensome. *See* ECF No. 102. To further support their relevancy argument, Plaintiffs also included an affidavit from an economist, Nicole Maestas, Ph.D., that Plaintiffs retained to opine on how the requested documents and data will be relevant to determine J&J's market power. *Id.*, attach. 2. Because Plaintiffs' reply brought forth new material, J&J filed a motion for leave to file a sur-reply, ECF No. 103, which the Court granted, ECF No. 109. J&J's sur-reply generally argued that Dr. Maestas was not qualified to make her opinions, and that her assertions were too conclusory or without external support. *See* ECF No. 110 at 3–6.

The Court held a hearing on the Motion to Compel on August 20, 2024. At the hearing, Plaintiffs initially represented that there had been no further narrowing of the issues in raised in the Motion to Compel. However, J&J represented that it agreed to produce documents for the relevant RFPs going back to 2016 after the Court issued its Memorandum Opinion and Order on August 16, 2024 (ECF No. 119), which granted in part and denied in part J&J's Motion to Dismiss.

II. LEGAL STANDARD

Pursuant the Federal Rule of Civil Procedure, "discovery is broad in scope and freely permitted." *Symbology Innovations, LLC v. Lego Sys.*, 158 F. Supp. 3d 916, 933 (E.D. Va. 2017)

(citation omitted). Specifically, Federal Rule of Civil Procedure 26(b)(1), provides that "[p]arties may obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense and proportional to the needs of the case[.]" Fed. R. Civ. P. 26(b). "[T]he threshold for relevance is not a high one[.]" *Contract Materials Processing, Inc. v. Kataleuna Gmbh Catalysts*, 462 F. App'x 266, 273 (4th Cir. 2012). In determining the scope of discovery, the Court considers "the importance of the issues at stake in the action, the amount in controversy, the parties' relative access to relevant information, the parties' resources, the importance of the discovery in resolving the issues, and whether the burden or expense of the proposed discovery outweighs its likely benefit." Fed. R. Civ. P. 26(b)(1). The party resisting discovery has the burden of establishing that the production should not be required. *Doe v. Old Dominion Univ.*, 289 F. Supp. 3d 744, 749 (E.D. Va. 2018) (citing *Singletary v. Sterling Transp. Co.*, 289 F.R.D. 237, 241 (E.D. Va. 2012)).

Additionally, "[t]he district court's discretion with respect to discovery matters is broad." *Vodrey v. Golden*, 864 F.2d 28, 32 (4th Cir. 1988) (citing *Ardrey v. United Parcel Service*, 798 F.2d 679, 682 (4th Cir. 1986)). In the Fourth Circuit, courts "enjoy nearly unfettered discretion to control the timing and scope of discovery[.]" *Ashland Facility Operations, LLC v. NLRB*, 701 F.3d 983, 994 (4th Cir. 2012) (quoting *Hinkle v. City of Clarksburg, W. Va.*, 81 F.3d 416, 426 (4th Cir. 1996)).

III. ANALYSIS

1. Relevance

Plaintiffs contend that the RFPs at issue dating back to 2011 are relevant for several reasons. First, Plaintiffs argue that Stelara was launched in 2009, and the clinical trial studying its use to treat ulcerative colitis—the basis of the '307 patent, and the basis of Plaintiffs' claim that J&J defrauded the USPTO—began in 2015. ECF No. 95 at 13–14. Accordingly, Plaintiffs

contend they need to ascertain the identities of key individuals involved in the patent application process before 2018 to show J&J was aware of ustekinumab's capabilities in treating ulcerative colitis before the 2018 priority date. *Id.* Second, Plaintiffs argue that the RFPs at issue dating back to 2011 will allow them to discover evidence of a history of high gross margins and supra-competitive prices to demonstrate J&J's market power—both at the time J&J acquired the Momenta patents in 2020, and for nearly a decade prior. *Id.* at 16–18. Third, Plaintiffs argue that they need documents to demonstrate J&J's internal perceptions of the "potential therapeutic competitors" at the time these drugs entered the market to counteract J&J's defense that these drugs are interchangeable with ustekinumab and in the same market. *Id.* at 18 n. 49 (identifying drugs J&J stated were "Competitive Products" and the year those drugs entered to the market). Plaintiffs contend that the RFPs at issue—seeking forecasts for biosimilar entry, forecasts for potential therapeutic competitors, and business documents analyzing the same—will help define the relevant market for ustekinumab. *Id.* at 19. These documents and data, created at the time the "potential therapeutic competitors" launched, will allow Plaintiffs to conduct "a natural experiment to calculate cross-price elasticities." ECF No. 102 at 15–16. Importantly, Plaintiffs contend that documents and data for these RFPs dating back to 2011 will capture J&J's perceptions of the market "without the taint of J&J's anticompetitive behavior." ECF No. 102 at 7.

In response, J&J originally argued that the documents Plaintiffs seek regarding J&J's market power in 2011 were not relevant to whether J&J possessed monopoly power in 2022 or 2023.[2] ECF No. 99 at 12–17. However, at the hearing, J&J agreed that the Court's Memorandum

[2] In large part, the parties focused their briefing on the relevant year to evaluate whether J&J "possessed monopoly power in the relevant market." *Compare* ECF No. 95 at 16–17 (arguing the proper year to consider whether J&J possessed monopoly power is 2020—when J&J acquired Momenta) *with* ECF No. 99 at 12–15 (arguing the proper year to consider whether J&J possessed monopoly power is 2022 or 2023—when J&J began to enforce the '307 patent and the Momenta patents).

Opinion and Order on J&J's Motion to Dismiss (ECF No. 119) determined that the relevant year to evaluate market power was 2020—when J&J acquired the Momenta patent portfolio—and accordingly agreed to produce the RFPs at issue going back to 2016. *See* ECF No. 124 at 38:14–39:1–7. J&J proffered that the key relevant question in this case is whether it had monopoly power in 2020. Although "potential therapeutic competitors" entered the marketplace between 2011 and 2016, J&J contends how it viewed those drugs at the time they were *launched* is irrelevant. Rather, the relevant inquiry is how J&J viewed those drugs as competition to ustekinumab in 2020 and just some years prior—making 2016 the appropriate date to fix the RFP production. J&J argued that if a drug launched in 2012 was still competitive with ustekinumab in 2016, the RFP production would encompass such documents and data. Accordingly, producing the RFPs dating back to 2011 would be irrelevant.

Here, the RFPs at issue are clearly relevant to Plaintiffs' claims and defenses. With respect to RFP Nos. 1–2, the organizational charts to determine the key players in obtaining the '307 patent are relevant to Plaintiffs' claims that J&J was aware of ustekinumab's ability to treat ulcerative colitis. With respect to RFP Nos. 78–83, 85–88, 90–92, and 101, those are clearly relevant to demonstrate Plaintiffs' claim that J&J "possess[ed] monopoly power in the relevant market" as required by Section 2 of the Sherman Act. *See E. I. du Pont de Nemours & Co. v. Kolon Indus.*, 637 F.3d 435, 450 (4th Cir. 2011). The documents and data Plaintiffs seek in the RFPs at issue are relevant to evaluate J&J's market power and to define which drugs are in the relevant market. Further, documents predating 2020 would be relevant in addressing J&J's market power over a sustained period.

2. Proportionality

Because the RFPs at issue are relevant, the burden is on J&J "to establish that the challenged production should not be permitted." *Doe*, 289 F. Supp. 3d at 749. J&J conceded that the cost to produce the organizational charts sought in RFP Nos. 1–2 back to 2011 would be minimal. ECF No. 99, attach. 1 at ¶ 54. However, J&J estimated that the cost to produce RFP Nos. 78–83, 85–88, 90–92, and 101 back to 2011 would be between $855,410.60 and $1,710,821.20. *Id.* at ¶ 53. In support of their burden argument, J&J outlined that it has many lawyers working extensive hours on the document production in this case, in addition to utilizing an outside eDiscovery vendor to manage the document production. ECF No. 99 at 17; ECF No. 99, attach. 1 at ¶¶ 44–51. J&J contends that the burden on it to produce this discovery outweighs its benefit, as documents and data going back to 2011 are not relevant. ECF No. 99 at 17.

Plaintiffs argue that their requested discovery is proportional to the needs of the case because J&J is the only source for some of the Stelara sales data, and only J&J's documents can demonstrate the complete picture of the market dating back to 2011. ECF No. 95 at 20. Further, Plaintiffs contend J&J has not demonstrated that producing the requested data is burdensome, particularly in light of the over $1 billion in damages they claim in this case and J&J's vast economic resources. *Id.* at 21–25. Plaintiffs argue that J&J has significant resources to complete the discovery requests, and that the cost is minimal in comparison to J&J's gross sales of Stelara—$7 billion in 2023 alone. ECF No. 102 at 21. At the hearing, Plaintiffs further emphasized the importance of RFP No. 92, and represented that it would be a "data pull" as opposed to a document pull, and accordingly J&J could simply produce the data without needing lawyers to review it for relevance or privilege.

3. Plaintiffs are entitled to the production of RFP Nos. 1–2, 78–83, 85–88, 90–92, and 101 dating back to 2014, and the production of RFP No. 92 dating back to 2011.

Considering the above analysis, the Court uses its discretion to control the timing and scope of discovery by compelling production of RFP Nos. 1–2, 78–83, 85–88, 90–91, and 101 dating back to 2014, and compelling production of RFP No. 92 dating back to 2011. Several considerations guide the Court's decision that 2014 is the proper year to fix the discovery date for the majority of Plaintiffs' RFPs, and that 2011 is the proper year to fix discovery for RFP No. 92.

First, with respect to all of the RFPs at issue, Plaintiffs have demonstrated that the documents and data they seek are clearly relevant to their claims and defenses in this matter. Specifically, J&J identified twenty-three "potential therapeutic competitor" products that purportedly competed with Stelara between 2011 and 2022, and J&J intends to include these products in the market definition to demonstrate that J&J did not have as much market power as Plaintiffs allege. The types of documents that the RFPs seek to produce—gross profit margins on Stelara, pricing strategies and decisions for Stelara, forecasts for biosimilar entry, forecasts for therapeutic competitors, and business documents analyzing therapeutic competitors—are clearly relevant to Plaintiffs attempt to define the contours of the biologics market, and to rebut any assertions by J&J as to the definition of the market.

Second, while the discovery is relevant and important, the Court recognizes that J&J's burden to produce the documents and data requested is not minimal. Although J&J did not provide a specific cost-estimate of production dating back to 2014, the Court can presume that it will be less than the range ($855,410.60–$1,710,821.20) that J&J estimated it would cost to produce documents dating back to 2011. That said, under Federal Rule of Civil Procedure 26(b)(1), the Court is permitted to consider the parties' resources. Here, J&J has the resources to make this production dating back to 2014, and to do so in a timeframe consistent with the scheduling order

in this case. Moreover, J&J conceded that it would not be burdensome to produce RFP Nos. 1–2, which seek organizational charts.

By fixing the discovery timeframe to begin in 2014, the Court can ensure the benefit of the discovery to Plaintiffs does not outweigh its burden of production to J&J. To the extent that "potential therapeutic competitor" products were launched in 2014 or beyond—such as Entyvio (2014), Otezla (2014), Consentyz (2015), Taltz (2016), Inflectra (2016), Siliq (2017), Kevzara (2017), and Tremfya (2017)—Plaintiffs will be able to obtain documents relating to J&J's perception of the competitiveness of those drugs with Stelara at the time of, or leading up to their launch. To the extent that other "potential therapeutic competitor" products were launched after 2011 but before 2014, for example, Xeljanz (2012), J&J's production will still encompass J&Js perceptions of their competitive standing with Stelara in 2014 and beyond.

Third, the key clinical trial studying the use of ustekinumab to treat ulcerative colitis began in 2015. That clinical trial is the basis of the '307 patent and Plaintiffs' claim that J&J defrauded the USPTO into incorrectly issuing the '307 patent. Thus, by fixing 2014 as the start date to produce the RFPs at issue, the documents and data will encompass any anticipated effect that clinical trial had on J&J's perception of the market. Moreover, by fixing the date in 2014, Plaintiffs will potentially receive some documents that they allege are "without the taint of J&J's anticompetitive behavior." *See* ECF No. 102 at 7.

Finally, with respect to RFP No. 92, at the hearing, Plaintiffs stressed the importance of RFP No. 92 to their case because it will produce the data that their economist needs to run "natural experiments." ECF No. 124 at 65:9–21. Plaintiffs also represented, and J&J did not dispute, that the production of RFP No. 92 constitutes a "data pull," as compared to a document pull, which greatly reduces J&J's burden of production for that RFP. *See id.* Thus, given the importance of

RFP No. 92, and the minimal burden of production to J&J, the Court finds it relevant and proportional to the needs of the case to permit Plaintiffs to go back to 2011 with respect to that RFP only.[3]

IV. CONCLUSION

For the reasons explained above, Plaintiffs' Motion to Compel, ECF No. 93, is **GRANTED IN PART** and **DENIED IN PART**. J&J is **ORDERED** to (1) complete its production for RFP Nos. 1–2, 78–83, 85–88, 90–91, and 101 dating back to 2014; and (2) to complete its production of RFP No. 92 dating back to 2011.[4]

The Court notes its appreciation that the parties' engaged in meaningful meet and confers, and its appreciation of the parties' willingness to further narrow their disputes as the litigation in this case continues. For example, following the briefing in this matter, Plaintiffs and J&J were able to resolve their dispute regarding documents related to the '734 patent, and following the Court's Memorandum Opinion on the Motion to Dismiss, J&J agreed to produce the RFPs at issue going back to 2016. The parties are encouraged to continue to work together to narrow any discovery disputes, and reminded to not engage in any discovery gamesmanship that would put this case schedule at jeopardy. Further, the Court reminds the parties that it is available informally in the event the parties would like to attempt to resolve any discovery disputes without the need for filing a formal discovery motion.

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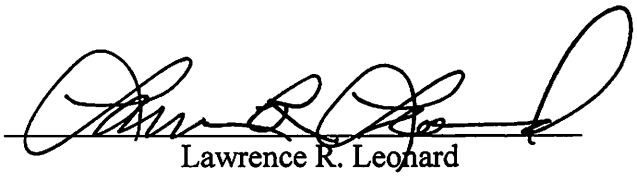
[3] At the hearing, the parties seemed to have a dispute regarding whether J&J agreed to produce RFP No. 92 back to 2011 solely in the form of profit and loss statements. *See* ECF No. 124 at 65:14–24, 77:8–25, 78:1–3. To be clear, the Court is ordering J&J to produce the data in RFP No. 92 to its full extent, in whatever form it exists.

[4] J&J requests that the Court "award all costs and attorneys' fees" related to its opposition to the Motion to Compel. ECF No. 99 at 26. Pursuant to Federal Rule of Civil Procedure 37(a)(5)(C), in the exercise of its discretion, the Court finds that attorneys' fees are not warranted.

The Clerk is **DIRECTED** to forward a copy of this Order to all counsel of record.

It is so **ORDERED**.



Lawrence R. Leonard
United States Magistrate Judge

Norfolk, Virginia
August 26, 2024